Food and Drug Administration (FDA)
Center for Devices and Radiological Health
Office of Science and Engineering Laboratories
Division of Biology, Chemistry and Materials Science

Subject: Position available at FDA for a research associate to study relationships between coating processing, properties and drug release from drug coated balloons (DCBs)

Background: Angioplasty balloons are inserted into blood vessels blocked by plaque and inflated to remove the blockage. The problem with this technique is that cell proliferation causes reblockage within 3-6 months after a balloon angioplasty in half the patients. To reduce this, balloons are coated with drugs that minimize cell proliferation. These drug coated balloons (DCB) are so new that there is little data regarding their safety and effectiveness, so there is the risk too much drug transferred to the blood vessel resulting in toxicity and destruction of the vessel or insufficient drug transfer, resulting in myocardial infarction and heart attack. This project will develop methods to predict how much and at what time during the clinical procedure the drug comes off the balloon and how manufacturing variables affect this.

Methods: In this project, balloons will be coated and tested in a simulated blood vessel. The effects of coating processing variables on coating properties and the amount of drug transfer to the blood vessel will be studied using Quality by Design (QbD) science methodology. QbD evaluates risks and key steps in the manufacturing process to improve product quality and to evaluate how the processing affects the coating properties and performance. The distribution of the drug in the balloon coating, drug crystallinity and the coating structure will be evaluated by DSC and scanning electron microscopy of the coating. The coating removed from the balloon during simulated insertion/inflation will be quantified by UV absorption and High Performance Liquid Chromatography (HPLC). We have conducted a similar QbD study on drug eluting stents (DES) [Martin McDermott, et al.; Application of Quality by Design (QbD) Approach to Ultrasonic Atomization Spray Coating of DES. AAPS PharmSciTech 2015 Aug;16(4):811-23].

Qualifications (in order of priority):

1. graduate or undergraduate student (junior or senior) studying science/engineering
2. experienced and confident working in the lab, dexterous at handling tools and setups
3. adept at independently solving problems, performing experiments and analyzing data
4. present at FDA a minimum of 50 hours/month during school and 160 hours/month during summer and committed to a minimum of 1 full summer and 1 full semester (longer if possible).
5. begin at as soon as possible, no later than June 6, 2016

Additional Information:

1. We provide training on specific instruments and techniques, e.g.: micropipetting, gravimetric mass measurements using high precision analytical balances, preparation of HPLC mobile phases, running samples on the UV-Vis spectrophotometer, analysis of HPLC and UV-Vis data.
2. All contributing to the results are coauthors in future publications.
3. This is a volunteer position, which may change to a paid position (at a rate based on degree of education) dependent on the applicant's skill level and experience.
4. We will work with your school so you may receive research credit.
5. Contact is Dr. Martin McDermott: Martin.McDermott@fda.hhs.gov; Phone (301) 796-2621; Fax: (301) 796-9924, 10903 New Hampshire Avenue, Silver Spring MD, 20993.